UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,894	02/20/2004	Louis S. Kucera	053665-5012	4211

9629 7590 01/16/2008

MORGAN LEWIS & BOCKIUS LLP
1111 PENNSYLVANIA AVENUE NW
WASHINGTON, DC 20004

EXAMINER	
ANDERSON, JAMES D	

ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
01/16/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/781,894	KUCERA ET AL.	
	Examiner	Art Unit	
	James D. Anderson	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) *9-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/ are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *15 sheets*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-39 are presented for examination

Election/Restrictions

Applicant's election of Group I (claims 1-8 and 39) in the reply filed on 11/1/2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 9-38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/1/2007 (see *supra*).

Applicant's election of the compound of Formula I wherein R_1 is –NHC(O)Y, where Y is C_{22} alkyl; R_2 is –OX, where X is C_{22} alkyl; and R_3 is phosphocholine in the reply filed on 11/1/2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). However, upon further consideration, search and examination have been extended to cover compounds of Formula I wherein Y and/or X are C_1-C_{22} alkyl, C_2-C_{22} alkenyl, and C_2-C_{22} alkynyl.

Status of the Claims

Claims 1-8 and 39 are presently under examination and are the subject of this Office Action.

Priority

The present application does not claim priority or benefit to any prior-filed applications. Accordingly, the earliest effective U.S. filing date afforded the instant application is 2/20/2004.

Information Disclosure Statement

Receipt is acknowledged of the Information Disclosure Statements filed 5/14/2004 and 10/22/2004. The Examiner has considered the references cited therein to the extent that each is a proper citation. Please see the attached USPTO Form 1449.

The following references as cited on the IDS filed 5/14/2004 were not considered because there is no date of publication: 1) Citation C10; 2) Citation C40; and 3) Citation C99.

Claim Rejections - 35 USC § 112 (1st Paragraph)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8 and 39 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a Written Description rejection.

Regarding the requirement for adequate written description of chemical entities, Applicant's attention is directed to the MPEP §2163. In particular, *Regents of the University of*

California v. Eli Lilly & Co., 119 F.3d 1559, 1568 (Fed. Cir. 1997), *cert. denied*, 523 U.S. 1089, 118 S. Ct. 1548 (1998), holds that an adequate written description requires a precise definition, such as by structure, formula, chemical name, or physical properties, "not a mere wish or plain for obtaining the claimed chemical invention." *Eli Lilly*, 119 F.3d at 1566. The Federal Circuit has adopted the standard set forth in the Patent and Trademark Office ("PTO") Guidelines for Examination of Patent Applications under the 35 U.S.C. 112.I "Written Description" Requirement ("Guidelines"), 66 Fed. Reg. 1099 (Jan. 5, 2001), which state that the written description requirement can be met by "showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics," including, *inter alia*, "functional characteristics when coupled with a known or disclosed correlation between function and structure..." *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 316, 1324-25 (Fed. Cir. 2002) (quoting *Guidelines*, 66 Fed. Reg. at 1106 (emphasis added)). Moreover, although *Eli Lilly* and *Enzo* were decided within the factual context of DNA sequences, this does not preclude extending the reasoning of those cases to chemical structures in general. *Univ. of Rochester v. G.D. Searle & Co.*, 249 Supp. 2d 216, 225 (W.D.N.Y. 2003).

In the instant case, the claims recite compounds of Formula I or "prodrug thereof". There is insufficient written description of the claimed prodrugs. Applicants provide no direction as to (a) what structural features constitute "prodrugs" of the claimed compounds and (b) which of chemically modified compounds actually *have* activity as prodrugs without having to execute hit or miss testing practices in order to make such a determination.

Although general techniques such as cellular assays may be known in the art, this fact fails to diminish the amount of experimentation that the skilled artisan would have to undertake

to even identify, let alone determine the full scope of, the claimed prodrugs, particularly in view of the fact that this genus as a whole is not one that is well-known or well-defined in the art such that the skilled artisan would readily envision those compounds that are within the scope of the claimed genus.

The need for testing amongst varying species of compounds to determine the full scope of the genus of prodrugs instantly claimed demonstrates that Applicants were not in possession of the full scope of the genus now presently claimed. "Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was 'ready for patenting' such as by disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the Applicant was in possession of the claimed invention." Please see MPEP § 2163.

Despite the disclosure of the compounds of Formula I, it remains that the specification provides non-limiting exemplification of a solely functional genus of agents that may be used within the context of the present invention. With the exception of the genus of compounds defined by Formula I in the original disclosure and claims, Applicants are imposing the burden of extensive testing upon the skilled artisan to identify those other agents that may act as prodrugs of the claimed compounds, but which Applicants have not identified and thus, were not in possession of, at the time of the present invention.

It has been held in patent law that a wish or plan for obtaining the invention as claimed does not provide adequate written description of a chemical invention. Rather, a precise definition, such as by structure, formula, chemical name or physical properties or a combination

thereof, is required. Please reference, e.g., *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 927, 69 USPQ2d 1886, 1894-95 (Fed. Cir. 2004). In other words, though Applicants may have a plan for how to identify other agents that may be amenable for use in the present invention, it remains that at the time of the invention, Applicants had not identified such compounds, and, therefore, did not have written description of the full scope of the genus claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-8 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Kucera *et al.*** (U.S. Patent No. 5,962,437; Issued Oct. 5, 1999; Filed Aug. 7, 1995).

The instant claims recite methods of treating RSV infections comprising administering a compound of Formula I.

Kucera *et al.* teach methods of treating viral infections comprising administering to a subject a phospholipid or phospholipid derivative (Abstract). Such phospholipid derivatives include compounds of Formula I, which encompass the compounds of Formula I as recited in the instant claims (col. 2, lines 4-35). For example, identical compounds of Kucera *et al.* and the instant claims are obtained when X is NHCO, $R_1 = C_6$ to C_{18} alkyl, Y is O, R_2 is C_6 to C_{14} alkyl, R_6 is CH_2CH_2 and R_3, R_4, and R_5 are methyl. Kucera *et al.* thus clearly anticipate using the claimed compounds of Formula I to treat viral infections. The compounds are taught to work via attachment to cell membranes and thus are particularly effective against infections caused by membrane-containing or envelope-containing viruses (col. 9, lines 42-45). While Kucera *et al.* exemplify the treatment of HIV-1 infections, the inventors state that the compounds of Formula I can also be used to treat the instantly claimed respiratory syncytial virus infections (col. 9, lines 56-61). With respect to claim 39, which recites modes of administration, Kucera *et al.* teach the same modes of administration (col. 10, lines 14-21).

Accordingly, the instantly claimed methods of treating RSV infections comprising administering a compound of Formula I would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made. Kucera *et al.* clearly motivate one skilled in the art to use compounds of Formula I to treat viral infections and even teach that respiratory syncytial virus infections are a type of infection that may be treated with the compounds of the invention. As such, and in the absence of a showing of unexpected results commensurate in scope with the claims, one skilled in the art would have been imbued with at least a reasonable

expectation that the compounds of Formula I as taught in Kucera *et al.* would be effective at treating viral infections, including the instantly claimed RSV.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

U.S. Patent No. 5,962,437

Claims 1-8 and 39 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 5,962,437. Although the conflicting claims are not identical, they are not patentably distinct from each other because the treatment of a "viral infection" in a subject with a compound of Formula I as recited in the claims of the '437 patent fully encompasses the subject matter instantly claimed. In this regard, the Examiner refers to the specification of the '437 patent as a dictionary to define what viral

infections the inventors contemplate treating. At column 9, lines 56-61, the instantly claimed respiratory syncytial virus infections are taught as one type of viral infection that may be treated with the compounds disclosed therein.

U.S. Patent No. 7,026,469

Claims 1-8 and 39 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 12, 17, 18, and 19 of U.S. Patent No. 7,026,469. Although the conflicting claims are not identical, they are not patentably distinct from each other because the treatment of a "viral infection" in a subject with a compound of Formula III as recited in the claims of the '469 patent fully encompasses the subject matter instantly claimed.

U.S. Patent No. 7,141,557

Claims 1-8 and 39 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 and 14-18 of U.S. Patent No. 7,141,557. Although the conflicting claims are not identical, they are not patentably distinct from each other because the treatment of a "viral infection" in a subject with a compound of Formula III as recited in the claims of the '557 patent fully encompasses the subject matter instantly claimed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James D. Anderson whose telephone number is 571-272-9038. The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

James D. Anderson
Patent Examiner
AU 1614

January 9, 2008

1/12/08

ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER